

**REMARKS**

Claims 50-64 are pending in the application.

Claims 1-49 have been canceled.

Support for new Claims 50-64 is in the original and previously pending claims and the specification of the published application US 2004/0137086 as follows: at [0009] [0049] (through estimation of body weight); at [0024] [0046] and Claim 22 (statistically significant; statistically analyzed for significance ( $p < 0.05$ )).

The new claims are merely to clarify the subject matter claimed. No new matter has been added.

**Rejection of Claims under 35 U.S.C. § 112(1)**

The Examiner rejected the claims under Section 112(1) for failing to comply with the enablement requirement. This rejection is respectfully traversed.

The Examiner argues that the claims contain subject matter not described in the specification such that one skilled in the art is not enabled to make and/or use Applicant's methods as claimed. This rejection is respectfully traversed.

Applicant's specification is sufficiently enabling for one of ordinary skill in the art to make and use the method as defined in the claims, and the practice of that method would not require undue experimentation.

To meet the enablement requirement, the specification must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation. *In re Wright*, 27 USPQ2d 1510 (Fed. Cir. 1993). The factors relevant to whether experimentation is undue are provided under *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988). See also, *Sanofi-Synthelabo v. Apotex Inc.*, 89 USPQ2d 1370 (Fed. Cir. 2008).

The claims require administering a defined odorant composition to a male person for inhalation – the odorant composition effective to lower the male's estimate of the body weight of an observed female person by a statistically significant amount (i.e.,  $p < 0.05$ ) compared to the male's estimate of the female's body weight in the absence of inhaling the odorant composition.

The claims also require that the odorant composition is hedonically positive to the male person, that the body mass index (BMI) of the female is about 25 or greater, and that the odorant composition comprises/consists essentially of a mixture of a floral odorant and a spice odorant.

The floral odorant of the mixture is *limited to* jasmine, lilac, lily of the valley, magnolia, rose, lavender, geranium, hyacinth, orange blossom, apple blossom, carnation and mixtures thereof, and the spice odorant is *limited to* cinnamon, ginger, cloves, nutmeg, oriental spice and mixtures thereof.

The Examiner argues that the method as described and claimed is not patentable based on the Examples (Pilot Study and Test Study), stating as follows in the Office Action at page 14, 1<sup>st</sup> full paragraph (emphasis added).

...the data presented in the specification indicate no significant results for the claimed process; and therefore one of skill in the art would not be able to make and/or use the method as instantly claimed.

The Examiner's position is also repeated in the Office Action at page 5, 2<sup>nd</sup> full paragraph, and again at page 20, 1<sup>st</sup> full paragraph, as follows:

...The Examiner must evaluate the data presented in the disclosure as it pertains to the claimed subject matter. Herein, Examiner's initial analysis finds the data presented in the disclosure provides no significant results for practicing the invention as claimed.

The Examiner questions the veracity of the working examples for demonstrating the results of Applicant's method.

The Examiner particularly addresses the Pilot Study and argues that the data from the Pilot Study fails to demonstrate results required by Applicant's method as claimed.

The Examiner particularly questioned the Pilot Study, arguing that it did not involve a female model having a BMI greater than 25 and the data did not demonstrate that the three odorants tested had an effect on the male observer's estimates of the female model as required by the claimed method. Office Action at page 7, lines 15-22.

The Examiner further argued that "the Applicant's idea for the 'workability' of the claimed invention is predicated on" the discussion of the results of the Pilot Study at page 16, lines 13-25 of the specification. Office Action at page 13, 2<sup>nd</sup> full paragraph.

That discussion addresses the results of the Pilot Study and teaches that the method of the invention "is more effective to alter perception of the body weight of individuals whose BMI is greater than 25.0..." This premise was then demonstrated in the Test Study by using a woman model having a higher BMI of 36.2.

It is well understood in the art that a "pilot study" typically serves as a preliminary study that is conducted before the main research in order to check the feasibility or to improve the

design of the research. A pilot study is often used to test the design of an experiment and can provide insight into conducting a test study or experiment.

As described at page 15, lines 8-14, the Pilot Study was conducted prior to the test study using a woman with a BMI of 23.0, and the data results demonstrated that regardless of the use of hedonically positive odorants, there was no significant effect on the male participants. The Pilot Study thus provided insight into conducting the subsequent Test Study. In effect, the Pilot Study serves as a comparative study to the Test Study.

Applicant discusses the results of the Pilot Study at page 16, lines 13-25 of the specification, which results demonstrated that inhaling a hedonically positive odorant did not significantly alter the estimation of body weight of a woman with a BMI of 23.0 by the male participants.

Using the information provided by the Pilot Study, in the Test Study described at pages 14-15, a woman model having a higher BMI of 36.2 was used in the testing of three hedonically positive odorant mixtures. The results of the Test Study demonstrated that the inhalation of a *floral and spice odorant mixture* by the *male participants*, who then observed and estimated the body weight of the woman model (*BMI > 25*), resulted in a statistically significant reduction in the estimation of weight compared to the blank control – as set forth in the claims.

As such, the Examples provide a working example of the implementation of the elements of Applicant's methods as set forth in the claims.

It is further pointed out that there is no requirement for a working example under the enablement requirement of Section 112(1). See MPEP § 2164.02 Working Example (*"Compliance with the enablement requirement of 35 U.S.C. 112, first paragraph, does not turn on whether an example is disclosed..."*). The specification need not contain an example if the invention is otherwise disclosed in such manner that one skilled in the art will be able to practice it without an undue amount of experimentation. *In re Borkowski*, 422 F.2d 904, 908, 164 USPQ 642, 645 (CCPA 1970). The proper inquiry under *In re Wands* is whether the disclosure of the application enables one skilled in the art to make and use the invention without undue experimentation.

The Examiner has failed to properly and fully consider Applicant's arguments regarding the teachings throughout the specification of how to conduct the method claimed. Applicant has

provided sufficient guidance and the requisite teachings to enable one of skill in the art to put into effect the method as claimed without undue experimentation.

The nature and characteristics of the listed odorants are well understood in the odorant arts, and one skilled in the odorant arts would readily ascertain and provide suitable odorants that have the recited odorant character from various sources – both synthetic and natural. The claims employ language known and used in the art and which is of the same scope as the described invention.

Applicant has cited to numerous patents and publications as evidence of how one skilled in the art uses and understands the terms jasmine, lilac, lily of the valley, magnolia, rose, lavender, geranium, hyacinth, orange blossom, apple blossom, carnation, cinnamon, ginger, cloves, nutmeg and oriental spice odorants, and to show the acceptance of these terms in the art, as well as the use and construction applied to these terms by the USPTO. Those publications include USP 5,885,614 (Hirsch), USP 5,904,916 (Hirsch), USP 5,324,490 (Van Vlahakis), USP 5,372,303 (Paul) USP 6,991,785 (Frey, II), USP 6,589,537 (Harbeck), and Doty (The Smell Identification Test™ Administration Manual, Philadelphia Sensorics, Haddon Heights, N.J., pages 5 and 7 (1983). Such publications demonstrate that the meaning and scope of the listed odorants are accepted and well understood in the odorant arts and by the USPTO.

Examples of sources of commercial odorants and essential oils within the scope of the claims have been described in the specification at page 6, lines 7-20. One of ordinary skill in the odorant arts would be able to readily ascertain other commercial and non-commercial sources of the odorants that fall within the scope of the claims, and whether a substance had a jasmine aroma, a lilac aroma, a lily of the valley aroma, a cinnamon aroma, a ginger aroma, an oriental spice aroma, or other odorant aroma as listed in the claims.

Additionally, methods are well known in the art for identifying and/or preparing odorants within the scope of the claims, as evidenced by the following previously submitted publications and referenced patents: Jordan et al., *J. Agric. Food Chem.* 49(10):4813-7 (2001); Zhou et al., *J. Agric. Food Chem.* 50(7): 2016-21 (2002); Hamilton et al., "Measuring Farmstead Odors," Oklahoma Cooperative Extension Service, OSU Extension Facts F-1740 (06-1999); *Kirk-Othmer Concise Encyclopedia of Chemical Technology*, John Wiley & Sons, Inc., p. 844 (1985); USP 5,031,764 (Meador) and USP 6,606,566 (Sunshine).

From the commercial sources and the other information provided by Applicant, one skilled in the odorant arts would readily produce and/or identify the specific floral and spice odorants listed in the claims and formulate a composition of a mixture of those odorants for administering to a male subject in accordance with the claimed methods.

Applicant has also described methods that can be used to assess and screen odorants and odorant mixtures for effectiveness in achieving the desired result, as described in the specification at page 6, lines 21-36 and page 7, lines 2-24. And, it is implicit that the conditions of the claimed method would not be met unless the odorant composition achieves the required effect.

In view of Applicant's description and with the knowledge in the art with regard to those odorants and preparing odorant compositions, one skilled in the odorant arts would readily ascertain and provide a suitable composition composed of a mixture of floral and spice odorants as required by the claims.

The specification further addresses the implementation of Applicant's methods by applying an odorant composition to the skin or clothing of a male subject for inhalation or presenting the composition to the male, for example, as a liquid or spray and as a 'scratch-and-sniff' or blister pack delivery system. See specification at page 8, lines 4-14 and page 10, lines 1-16.

The elements of Applicant's method as claimed are sufficiently disclosed in the specification as originally filed. It would be a routine matter for one of ordinary skill to prepare and administer an odorant composition as defined in the claims, and readily determine without undue experimentation whether the composition worked or not and whether the method practiced is within the scope of the claims.

Based on Applicant's disclosure and the understanding in the art, Applicant has provided sufficient guidance and the requisite teachings to enable one of skill in the art to put into effect the method as claimed without undue experimentation.


Accordingly, the Examiner is requested to reconsider and then withdraw this rejection of the claims.

**Extension of Term.**

The proceedings herein are for a patent application and the provisions of 37 CFR § 1.136 apply. Applicant believes that a three-month extension of term is required. Please charge the required fee (large entity) to Account No. 23-2053. If an additional extension is required, please consider this a petition therefor, and charge the required fee to Account No. 23-2053.

It is respectfully submitted that the claims are in condition for allowance and notification to that effect is earnestly solicited.

Respectfully submitted,



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